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(בעברית) מתקן ושיטה לפונדופליקציה אנדוסקופית
(Hebrew)

(באנגלית) ENDOSCOPIC FUNDOPLICATION DEVICE AND METHOD
(English)

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מתקן ושיטה לפונדופליקציה אנדוסקופית

ENDOSCOPIC FUNDOPLICATION DEVICE AND METHOD

FUNDOPLICATION APPARATUS AND METHOD

Field of the Invention

The present invention relates to endoscopic apparatus. More particularly, the invention relates to an apparatus and a method for the endoscopic fundoplication for the treatment of gastroesophageal reflux disease (GERD).

Background of the Invention

GERD is caused by abnormal regurgitation of acid fluids from the stomach into the esophagus. The stomach generates strong acids to aid digestion. The esophagus is normally protected from these acids by a one-way valve mechanism at its junction with the stomach. This one–way valve is called the lower esophageal sphincter (LES). In patients with GERD, the LES frequently malfunctions because it is either too weak or too short. The short or weak LES cannot retain the contents of the stomach as it fills up and pressure inside rises.

When the LES fails, acid flows backwards - refluxes - up into the esophagus which is not designed to handle it. The result is an acid burn, commonly called "heartburn", or "acid indigestion". Heartburn feels like a burning or pressure pain behind the breastbone – it may feel very much

like a heart attack. When the acid is in the esophagus, and one belches, it may regurgitate up into the back of the throat, tasting sour or bitter, and causing a burning sensation. If this occurs at night, one may wake-up with either a hot, fiery feeling in the back of the throat, or even coughing and gasping resulting from acid entering the breathing tubes. This last phenomenon is called Reflux Nocturnal Aspiration and can be quite serious in itself.

Reflux Nocturnal Aspiration can be dangerous, because it introduces acid and bacteria into the airway and lungs. This can cause recurrent bronchitis, pneumonia, lung abscess, or chronic scarring of the lung. It can also lead to asthma attacks in those with an asthmatic tendency.

When acid reflux and these symptoms occur daily or up to three or four times a weekly, the esophagus cannot withstand the damaging effects of the acid bath and becomes inflamed, especially at its lower part. Swallowing can frequently be painful, and food may stick in the chest. This is called *reflux esophagitis,* meaning inflammation of the esophagus due to acid reflux. Persistent esophagitis can cause erosions and ulcers and lead to scarring and narrowing and also irreversible injury to the esophagus.

In some patients, as the esophageal lining becomes increasingly damaged and the body may attempt to try to protect it by changing the lining material to a more resistant type, such as found in the intestine. This change, called *Barrett's Esophageal Metaplasia*, or *Barrett's Esophagus*, does not make the symptoms disappear but actually produces a new problem. Metaplastic changes increase the risk of a cancer forming in the new and abnormal lining. *Adenocarcinoma of the Gastresophageal Cardia* is a highly malignant and fatal type of cancer, the incidence of which is increasing rapidly in America. Some authorities believe that Barrett's esophagus is caused by bile reflux and that the rising incidence of this particular type of cancer is due to the increasing use of medication that suppresses acid production, thus allowing the alkaline bile to reflux unopposed into the esophagus.

The symptoms of acid reflux are uncomfortable, and some sort of relief is usually sought. Some patients chew antacid tablets, sleep on several pillows, or even sleep upright in a recliner. Those with frequent symptoms are treated with drugs that interfere with the formation of acid in the stomach such as Tagamet®, Zantac®, Pepcid®, and Prilosec®. These medications work well in relieving symptoms, till the next dose is due, but they have to be taken daily, often for life, and the cost is substantial (around $1,300 per patient per year).

Moreover, these medications relieve the symptoms, but do not correct the underlying problem.

Currently, the only way to restore the valve function is to operate under a general anesthetic. In the past, the operation was a complex undertaking, entailing a large abdominal or thoracic incision, a lengthy stay in hospital, and a prolonged absence from work. Today, the operation can be done laparoscopically. This shortens the hospital stay, from about ten days to two or three days, but is still carried on under a general anesthetic, and is associated with a significant complication rate. Therefore gastroenterologists are often reluctant to refer patients to surgeons for anti–reflux surgery and many patients who should be operated upon are not.

It is estimated that in the USA alone, 65 million people suffer from heartburn and GERD symptoms are currently the most common complaint of patients who consult with gastroenterologists. According to the New England Journal of Medicine, nearly 40% of adult Americans suffer from heartburn; of those who seek treatment for symptoms of reflux esophagitis, 10 to 20% have serious complications (about 4-8% of the total adult population).

The Prior Art

SURGICAL TREATMENT OF REFLUX ESOPHAGITIS

Surgical procedures are usually effective in controlling severe gastresophageal reflux disease. Surgical procedures are designed to correct gastresophageal reflux by creating a new functional lower esophageal sphincter and to repair a hiatal hernia when present. The most popular approach is the Nissen fundoplication or a modification of this technique [***The Esophagus***, 3rd Ed., Donald O. Castell, Ed., pp. 515-517]. It involves mobilization and wrapping of the fundus of the stomach around the lower esophagus. As pressure increases in the stomach it compresses the lower esophagus, preventing reflux. The procedure is performed after first placing a large dilator in the esophagus in order to prevent making the wrap too tight. Fundoplication performed by either a traditional open or laparoscopic technique should be identical, except that access to the esophagus by laparoscopy is through a series of four or five punctures, rather than by an upper abdominal incision. The advantages of the open technique include the ability to see structures in three dimensions and to palpate them. Laparoscopy provides a clear magnified view of the area of surgery and is associated with less pain and more rapid recovery postoperatively.

This procedure is illustrated in Fig. 1. The length of the suture "S" is 2.5 to 3.0 cm, and 2 to 5 sutures are typically required. Because wrapping the stomach "ST" 360 degrees around the esophagus "E", as shown in Fig. 1, is associated with inability or difficulty in belching and vomiting, partial fundoplications have been devised. These include the Toupet posterior partial fundoplication (270 degrees) [*Ibid*, pp. 517-518] illustrated in Fig. 2, in which "E" is the esophagus, AW is the anterior wall of wrap sutured to the esophagus, and "GJ" is the gastroesophageal junction, and the Thal anterior fundoplication (180 degrees), illustrated in Fig. 3, where "F" indicates the fundus being plicated.

All these procedures have an excellent track record in terms of safety, and ability to control both biliary and acid reflux. However, they can only be carried out laparoscopically or via a laparotomy (abdominal incision) or a thoracotomy (opening the chest). Either way, general anesthesia is required. Because of this disadvantage, the art has attempted do devise minimally invasive methods and apparatus that can be used to carry out fundoplication procedures. US 5,403,326 describes a fundoplication method of the stomach to the esophagus that requires the introduction of an esophageal manipulator and a stapler into the stomach lumen, and the stapling the intussusception esophagus to the stomach. US 5,558,665, and its related patent US 5,787,897, disclose a variform intraluminal

member that can be used to manipulate the fundus to a position where it can be fastened by other devices, and a method for carrying out such surgery. US 5,571,116, and its related patent nos. 5,676,674 and 5,897,562 describe a multi-stapler device, and associated staplers, for carrying out an automatic approximation of the lower esophagus and fundus of the stomach and for invaginating the gastroesophageal junction into the stomach, thereby involuting the surrounding fundic wall.

Notwithstanding the great efforts made in the art to overcome the need for major surgery in the treatment of GERD, none of the abovementioned devices and methods have gained any actual popularity, and they are currently not in use. The reasons for this fact are many, and include the difficulty in controlling the operation of the device, the inherent disadvantages of the types of fundoplications that can be achieved by them, the ongoing need for additional invasive operations, particularly the laparoscopic introduction of devices, etc. It is therefore clear that there is a need in the art for a fundoplication method that can be effectively used for the treatment of GERD, and which is free from the above disadvantages of prior art methods and devices.

It is therefore an object of this invention to provide a device and method using it, for the treatment of GERD, which overcome the aforementioned drawbacks of the prior art.

It is another purpose of this invention to provide fundoplication surgical apparatus that can be operated quickly and effectively, without the need for general anesthesia.

It is yet another object of the invention to provide surgical apparatus for the treatment of GERD that can be operated ambulatorily without the need for expensive operating rooms.

It is a further object of the invention to provide a method and apparatus for the partial fundoplication of the fundus of a patient's stomach.

Other purposes and advantages of this invention will appear as the description proceeds.

Summary of the Invention

In one aspect, the invention is directed to an endoscopic device for the partial fundoplication, comprising:

- a distal bending portion and a flexible portion suitable to be positioned in extended shape within the esophagus of a subject;

- a positioning assembly comprising two separate elements, one of which is located on said distal bending portion, and the other on said flexible portion;

- a stapling assembly comprising a staple ejecting device, wherein said staple ejecting device is located on either said bending portion or on said flexible portion, said staple ejecting devices being in working

positioned relationship when said two separate elements of said positioning assembly are aligned; and

- circuitry for determining when said two separate elements of said positioning assembly are aligned.

According to a preferred embodiment of the invention, the stapling assembly further comprises an anvil, wherein one of said anvil and of said staple ejecting device is located on said bending portion, and the other is located on said flexible portion, said anvil and said staple ejecting devices being in working positioned relationship when said two separate elements of said positioning assembly are aligned.

Preferably, but non-limitatively, the device of the invention comprises safety means for disabling the operation of the staple-ejecting device when the two separate elements of the positioning assembly are not aligned.

The device of the invention should preferably comprise viewing means, typically a video camera. As will be apparent to the skilled person, it is usually necessary to provide illumination apparatus for viewing purposes. These, however, are conventional, and are therefore not discussed herein in detail, for the sake of brevity. Additionally, conventional endoscopic devices and accessories can be provided, such as water and/or air supply and/or suction.

According to a preferred embodiment of the invention the endoscopic device further comprises a positioning assembly to position a portion of a stapling assembly within the esophagus at a location of about 5-6 cm above the gastroesophageal junction, when the endoscopic device is in working position. In a preferred embodiment of the invention said portion of the stapling assembly comprises an anvil.

The said portion of the stapling assembly can be displaced along the axis of the endoscopic device by various means. According to a preferred embodiment of the invention this is achieved by the action of a flexible threaded cable coupled with a female thread located in said portion of stapling assembly. In one preferred embodiment of the invention the flexible threaded cable is located within the endoscopic device, and is in contact with the female thread through a slit provided in the wall of the body of the endoscopic device. In another alternative preferred embodiment of the invention the flexible threaded cable is embedded in the external wall of the endoscopic device, and is in direct contact with the female thread of the portion of the stapling assembly.

In one preferred form of the invention the flexible threaded cable is rotated using a micrometric assembly, thereby to displace the portion of the stapling assembly positioned within the esophagus by a controlled distance.

The anvil will be often located within the esophagus, and can be of any suitable shape. According to a preferred embodiment of the invention the anvil is essentially ring-like in shape.

The distal portion of the positioning assembly can be located at different positions on the distal end of the endoscopic device. According to a preferred embodiment of the invention said distal portion of the positioning assembly is located on the distal tip. According to another preferred embodiment of the invention the distal portion of the positioning assembly is located on the outer wall of the distal tip.

Similarly, the distal portion of the stapling assembly can be located at different positions on the distal end of the endoscopic device. According to a preferred embodiment of the invention said distal portion of the stapling assembly is located on the distal tip. According to an alternative preferred embodiment of the invention the distal portion of the stapling assembly is located on the outer wall of the distal tip.

In another aspect the invention is directed to a method for carrying out an endoscopic partial fundoplication of the fundus of the stomach of a patient, comprising the steps of:

a) providing an endoscopic device comprising a bending portion and a flexible portion, a positioning assembly comprising two separate elements, and a stapling assembly comprising a staple ejecting device;

b) moving the distal tip of said endoscopic device so as to engage the fundus of the patient and to displace it toward the lower part of the esophagus;

c) bringing said stapling assembly into working positioned relationship by aligning said two separate elements of said positioning assembly located one on the bending portion and the other on the flexible portion of said endoscope;

d) determining when said two separate elements of said positioning assembly are aligned by maximizing a signal resulting by bringing them into close positioned relationship and received at a signal receiving and analyzing circuit cooperating with said positioning assembly;

e) ejecting a plurality of staples from said staple-ejecting device, thereby to connect the tissue between them; and

f) rotating the endoscopic device relative to the axis of the esophagus and repeating steps (c) through (e) for as many times as needed to achieve the desired partial fundoplication.

According to a preferred embodiment of the invention the stapling assembly further comprises an anvil, wherein one of said anvil and of said staple ejecting device is located on said bending portion, and the other is located on said flexible portion.

In one preferred embodiment of the invention the signal resulting by bringing the two separate elements into close positioned relationship is maximized by measuring a physical parameter which is a function of the distance. In another preferred embodiment of the invention the signal

resulting by bringing the two separate elements into close positioned relationship is maximized by correlating it to a measured physical parameter.

The invention also encompasses a method for positioning the endoscopic device of the invention in pre-aligned working position, comprising the steps of:

A) introducing the endoscopic device through the mouth of a patient and locating the position of the gastroesophageal junction;

B) determining the distance from a reference point located on the endoscopic device, and the gastroesophageal junction;

C) introducing the endoscopic device into the stomach by a length below the gastroesophageal junction sufficient to permit the distal tip to be flexed into a position where the fundus is pushed toward the esophagus;

D) locking the endoscopic device such that it cannot move relatively to the axis of the esophagus;

E) determining the position of the portion of the stapling assembly positioned within the esophagus using its original axial location, the distance determined in step B) above, and the radius of curvature of the distal portion of the endoscopic device; and

F) displacing said portion of the stapling assembly so as to position it in the range of about 5-6 cm above the gastroesophageal junction.

All the above and other characteristics and advantages of the invention will be further understood through the following illustrative and

non-limitative description of preferred embodiments thereof, with reference to the appended drawings.

Brief Description of the Drawings

- Fig. 1 illustrates the prior art wrapping of the stomach 360 degrees around the esophagus;
- Fig. 2 illustrates the prior art Toupet posterior partial fundoplication (270 degrees);
- Fig. 3 illustrates the prior art Thal anterior fundoplication (180 degrees);
- Fig. 4 schematically illustrates a conventional endoscope;
- Fig. 5 schematically illustrates the fixed portion and the bending distal portion of the device of the invention;
- Figs. 6A and 6B schematically illustrate the mechanical procedure involved in the fundoplication using a device according to the invention;
- Fig. 7 schematically illustrates the positioning of the device prior to stapling;
- Figs. 8A - 8D illustrate the various possible mismatchings in the positioning of the device;
- Fig. 9 schematically illustrates the stapling procedure;
- Fig. 10 schematically illustrates the operation of an endoscopiuc device according to another preferred embodiment of the invention;
- Fig. 11 illustrates the positioning of the device of Fig. 10;
- Fig. 12 shows the arrangement of the tip of the device of Fig. 11;
- Fig. 13 illustrates the positioning procedure of the anvil in the esophagus, according to a preferred embodiment of the invention;

- Fig. 14 is a biter, used in a procedure according to a preferred embodiment of the invention;
- Fig. 15 illustrates the fine positioning of the anvil within the esophagus; and
- Fig. 16 is a block diagram of an ultrasonic positioning assembly, according to a preferred embodiment of the invention.

Detailed Description of Preferred Embodiments

The invention will now be illustrated through the illustrative and non-limitative description of preferred embodiments. The invention employs many elements, such as the endoscopic base elements and the surgical stapler, which are well known in the art, and which are therefore not described here in detail, for the sake of brevity. A conventional endoscope is illustrated in Fig. 4. This endoscope comprises several features, such as the operating switches, the angulation lock, etc., that may be present in the device of the invention, but that will not be described in detail in the description to follow, because they are conventional and well known to the skilled person. Thus in the following description only elements needed to illustrate the invention will be described. Briefly, however, the endoscope illustrated in Fig. 4A and generally indicated at 40, is provided with a control section 41 provided with suction valves, locks, switches, etc., switches 42-45 being marked for illustration purposes. It also comprises a connector section 46, used to connect air and water inlets, light guides, etc., the light guide being indicated at 47, for illustration purposes. The insertion tube 48 consists of three separate sections: a flexible portion 49, a bending section 50 and a

distal end 51. These latter three sections are shown in greater detail in Fig. 4B, which also indicates the distal tip 52 in which the distal end 51 resides.

Looking now at Fig. 5, the distal portion of the device of the invention is schematically shown. This portion comprises a bending section, indicated at "b", and a fixed, non-bending section, indicated at "f". The bending portion can be of any suitable type, e.g., as that shown in Fig. 4(a), or as described in the aforementioned US 5,787,897. The fixed section, f, contains a first element of a stapling assembly, 1, the counterpart of which, 1A, is located near the distal tip 3 of the bending section, b. Stapling elements 1 and 1A, together, form the entire stapling assembly, to be discussed in greater detail below. Similarly, the fixed section f contains a fist positioning element 2, which together with its counterpart 2A, located in this particular embodiment near the distal tip 3 form the entire positioning assembly, to be discussed in greater detail below. Positioning elements 2 and 2A can be located at any suitable location along the respective sections b and f of the device (e.g., either below or above elements 1 and 1A), provided that when the two elements 1 and 1A of the stapling assembly are in working positioned relationship, said two elements 2 and 2A are also in working positioned relationship.

Positioning markings 4 may be located on the device, at the extremity outside the patient, to provide information on the length of device that has been introduced into the patient. Endoscopic vision means (not shown) can also be provided, to image the fundus of the stomach and to

determine the distance from introduction to the GE junction for each specific patient. These means are conventional of endoscopic apparatus, and are therefore not described herein in detail.

The device of the invention has three particularly important areas of operation: 1) the mechanical operation of the device, to bring it into the generally desired position; 2) the positioning operation, to position it in the exact desired location prior to surgical operation; and 3) the surgical operation which typically - but non-limitatively - involves the stapling of living tissue. These operations will now be described in detail.

Mechanical Operation of the Device

The mechanical operation of the device involves the bending of the bendable section of the device so as to engage the fundus of the stomach with the distal tip 3, and to move it toward the lower esophagus. This is schematically illustrated in Fig. 6 (A and B). In Fig. 6A two positions of the device are shown, a and a'. Position a is the initial position after the device has been inserted the whole of its desired length of insertion. Position a' illustrate the beginning of bending of bending section b of the device, towards the fundus 5, the tip being indicated as 3'.

In Fig. 6B the situation shown is that in which bending of the device has been completed, and the distal tip 3 has caused the fundus 5 to move from its original position to a position near the lower esophagus. In this position, if the fundus is correctly positioned by tip 3, it is possible to

carry out the stapling together of the fundus and esophagus. This procedure may have to be repeated once or more than once to achieve about 180° of fundoplication.

The Positioning Operation

The positioning operation is the most critical step in the procedure. This can be explained by looking at Fig. 7. In the figure, a device according to a preferred embodiment of the invention is shown, in which a stapling assembly 1, 1A is shown, as well as a positioning assembly 2, 2A, located on the endoscopic device generally indicated at numeral 6. It should be noted that the order of these two assemblies is inverted, as compared to that of Fig. 5, to illustrate that the order is not critical.

In order to fasten the lower part of the fundus 5 to the lower part of the esophagus 7, by means of stapling assembly 1, 1A (the operation of which will be described below) it is imperative that element 1 and element 1A be brought into the correct working positioned relationship, so that the staples, when ejected, perform their required task. Failure to bring the parts of the stapling assembly into the correct positioned relationship may be fatal, as it will result in the staple not being correctly positioned or folded, and in a high risk of damaging the tissue where the stapling has been performed.

The possible mismatching of the sections of the device is illustrated in Fig. 8. Fig. 8A shows the desired situation, in which the two elements, 2

and 2A, that form the positioning assembly, are aligned one with the other, thus bringing the device into working conditions. As schematically seen in Fig. 7, aligning of the positioning assembly results in a corresponding aligning of the stapling assembly.

Fig. 8B shows a situation in which an angular movement has occurred at the elbow 8 of the device of Fig. 7, resulting in a misalignment of magnitude "d" between the positioning elements. In Fig. 8C a rotational mismatching is shown, in which the bending section of the device has also rotated along its axis by an angle θ, again resulting in a comparable misalignment of the stapling assembly. Finally, Fig. 8D shows the situation in which the distal tip 3 of the device has not been pushed up sufficiently, and a misalignment of height "h" has occurred. All these occurrences must be avoided, since any of them is hazardous and will not obtain the desired result.

According to the invention, therefore, the aligning assembly consists of two elements that, when brought into an alignment such that the elements of the stapler assembly are aligned permits to actuate the stapler. According to a preferred embodiment of the invention the elements of the positioning assembly are ultrasonic elements, i.e., an ultrasound transducer and a receiver. A simple analysis of the ultrasound signal received at the receiver makes it possible to determine the maximal signal, which corresponds to the exact alignment. According to another preferred embodiment of the invention, one of elements of the positioning assembly emits light and the other is a photosensitive element

that translates the received light into a signal. Again, the maximal intensity of the signal indicates the maximal alignment.

According to still another preferred embodiment of the invention, one of the elements of the positioning assembly is a piezoelectric transducer, and the other is a simple protrusion. Application of a pressure by the protrusion on the piezoelectric transducer, via the thin tissue, generates an electric signal which, again, can be analyzed to determine its maximal value.

It should be mentioned that, in certain types of positioning assemblies, e.g., if it were desired to employ an RF assembly, it is not at all necessary that the two elements, 2 and 2A, be physically aligned as shown in Fig. 8A, viz., such that their physical centers are essentially aligned. When the alignment procedure does not rely on a physical, center-to-center matching, elements 2 and 2A could be positioned differently on the two sections of the device, provided that when they generate an output signal representative of maximal alignment, elements 1 and 1A of the stapling assembly are indeed physically aligned.

As will be appreciated by the skilled person, many different alignment schemes can be devised, for instance, using RF signals to determine the alignment position, or using a magnetic field generator on the one side, and a magnetic field positioning sensor on the other.

Surgical Operation

The surgical operation will be illustrated herein with reference to the stapling of tissue, for the sake of simplicity. It should be understood, however, that the invention is by no means limited to stapling, and that any other operation capable of connecting tissue, so as to bring the fundus into juxtaposition with the lower part of the esophagus - e.g., suturing with a needle, can also be employed. However, stapling is the most convenient procedure in common use for this type of surgery, and therefore will be used herein to illustrate the invention.

Fig. 9 shows the relevant part of the device and tissue. In Fig. 9A element 1, which in this case is the anvil, is aligned with element 1A, which in this case is the stapler. Of course, the two elements could be inverted since the operation of the stapler would be exactly the same in both cases. Stapler 1A may have been kept covered by a retractable cover 9, to avoid infiltration of foreign material, until the two elements are aligned and ready to use. Actuation of elements in an endoscope, such as that of cover 9, is well understood by the skilled engineer, and is therefore not discussed herein, for the sake of brevity

Fig. 9B shows the situation after the stapling has been effected. Staples, collectively indicated at 10, have engaged between the fundus and the esophagus, at the specific location on which it was operated. It is now possible to move the device by rotating it to its next location (i.e., by moving it in a direction perpendicular to the plane of the cross-section of

Fig. 6. When the next location is reached, the aligning procedure is repeated, and the stapling is effected again.

Surgical staplers are well known in the art, and are therefore not described herein in detail. Examples of suitable surgical staplers can be found in the aforementioned U.S. patents.

It should further be noted that anvil-less staplers can also be provided. This type of stapler is well known in the art and is manufactured, for instance, by Design Standards Corporation, USA. In such a case, of course, there is no need to align the stapler and the anvil, since no anvil is needed. However, it is still needed to position the two elements of the positioning assembly in the correct positioned relationship, since otherwise the wrong tissue portion may be stapled. Accordingly, all positioning operations described herein are relevant for both staplers with and without an anvil. Whenever reference is made in this description to either type of stapler it should be understood that the same applies, *mutatis mutandis,* to the other type, and the relevant part of the description will be not repeated, for the sake of brevity.

Another preferred embodiment of the invention is described in Fig. 10, which represents the same situation as described above with reference with Fig. 6B, but when using a bending end made of joints which have a radius of curvature such that, when brought into the position shown in Fig. 11, the tip 30 of the end part of the bending portion of the device (portion "b" of Fig. 5) is not parallel to the fixed portion (portion "f" of Fig.

5), as shown in Fig. 6B, but rather its tip 30 is positioned in front of elements 1 and 2 (Fig. 5). Such bending end and tip can be, e.g., similar to those shown in Fig. 4B.

Fig. 11 schematically illustrates the positioning of the device, according to this preferred embodiment of the invention. Positioning element 2A, located on tip 30, is brought into position in front of positioning element 2, located in the fixed portion of the device.

Fig. 12 schematically illustrates a tip 30, according to a preferred embodiment of the device of Fig. 11. The tip comprises positioning element 2A (positioned at the center in the figure, but which can be positioned elsewhere), element 1A of the stapling assembly, a lighting element 31, which may be, e.g., an optical fiber, air suction and/or water dispensing opening 32, and a video camera 33.

Introduction Procedure

The procedure through which the endoscopic device is introduced and brought into a generally aligned position (prior to using the positioning assembly 2-2A), will be briefly explained, using a simplified example, with reference to Fig. 13.

When in working position, stapling element 1 (referred to as the anvil in this example), must be located at a distance "y" from the gastroesophageal junction GJ which varies between about 5-6 cm, while the total length of

the esophagus typically varies between about 35-50 cm, depending on the subject. In order to determine the exact length "y", the GJ is identified, when first introducing the device, by visual inspection, e.g., via video camera 33 of Fig. 12. The total length of the device introduced at this stage is determined by reading the value indicated on the positioning markings 4, as also explained with reference to Fig. 5. Knowing the total length of the endoscopic device, its radius of curvature, "r", and the exact position of the GJ, makes it possible to determine the exact position of the anvil 1 relative to the length of the endoscopic device.

The endoscopic device 6 is then advanced to the desired position, and is then fixed using a constraining device, such as a biter illustrated in Fig. 14. The biter, shown in cross-section and generally indicated at 60, has a biting portion 61 which is held between the teeth of the patient. The endoscopic device (not shown) is introduced through the biter via an appropriate opening 62. When the device has reached the desired position the endoscopic device is caused to remain in its position by fixing it to the biter using conventional clamping means (not shown).

It is now necessary to move the anvil 1 so as to bring it into the desired position, i.e., 5-6 cm above the GJ. This is done, according to a preferred embodiment of the invention, using an arrangement such as that shown in Fig. 15. Fig. 15A shows a section 50 of the endoscopic device, which is provided with a slit 71 through which a threaded cable can be introduced. This is schematically shown in Fig. 15B, where the anvil 1 is mounted on threaded cable 72, coupled with a female thread located in anvil 1.

Threaded cable 72, which is flexible, reaches a micrometric displacement assembly (not shown), positioned before the biter, at end 35 of the device. By actuating the micrometric displacement assembly, knowing the patient's esophageal length and the position of the GJ, anvil 1 can be exactly positioned 5-6 cm above the GJ, in general pre-aligned position with the other half of the stapling assembly, 1A. Fig. 15C is a top cross-sectional view, showing the body 70 of the assembly device, the threaded cable 72, and a circular anvil 1.

Ultrasound Positioning Assembly

As explained above, one of the most preferred types of positioning assemblies is based on ultrasound waves. This is because of the relative simplicity of use of ultrasound transducers, which are used in several medical uses, and the safety of use that can be attained under appropriate conditions. It should be appreciated that the desired precision of the positioning of the mechanical elements described above is not less than 0.5 mm, to ensure that the stapler and its anvil are correctly positioned in a facing position, and this precision is within the scope of ultrasound equipment.

A preferred embodiment of the invention, comprising an ultrasound positioning assembly, will now be described for the purpose of illustration. Reference is made to Fig. 5, in which the two parts of the positioning assembly are indicated as numerals 2 and 2A. For the sake of this description we shall assume that the transmitter is element 2A, and the

receiver is element 2. The transmitter transmits at any physiologically acceptable frequency. An illustrative example of suitable frequencies are those in the range 3 - 20 MHz. The beam of ultrasound energy should be focused. This can be done by adding an ultrasonic lens, or by using a phase array.

The receiver 2 is positioned on the other side of the tissue, as shown in Fig. 7. This receiver consists of a directional transducer,, or an array of transducers, or a combination of both. The signal received at receiver 2 from transmitter 2A is analyzed, and its value is determined, as is also the distance between elements 1A and 1. A typical distance before stapling takes place is 0.5 - 1.5 cm. When scanning with transmitter 2A the space in front of receiver 2, a maximal signal is received when the two elements are at the maximal alignment position. When the maximum is attained, this signifies also that the stapler and its anvil are aligned, and stapling may take place. It should be noted that the anvil (or the stapler, depending on which of the two elements has been positioned on fixed portion "f" of Fig. 5) has been previously positioned so as to be at the correct location with respect to the tissue to be stapled. Thus, at this point the anvil, the stapler and the tissue between them are all correctly positioned. It should further be noted that the distance between the stapler and the anvil is also known, by measuring the time needed to the pulse to travel from one portion of the positioning assembly to the other.

The ultrasound assembly may be built in two alternative forms:

1. An assembly in which the antenna is common to both transmitter and receiver; and
2. An assembly in which each of the receiver and the transmitter has its own antenna (hydrophone for receiver and projector for transmitter).

Both assemblies are the same for the purposes of the invention, but each presents different technological advantages that will be discussed briefly below. In the second case lower energy of transmission is required, as compared with the first case. In the first case, on the other hand, an ultrasonic reflecting material, such as an ultrasonic mirror, can be positioned on the receiving side of the positioning assembly, so as to permit to reduce the energy of transmission.

The attenuation of the ultrasonic wave is directly dependent from the frequency. An ultrasonic wave passing through a living tissue decays approximately according to the ration 1dB cm^{-1} MHz^{-1} [*"Physical Principles of Medical Ultrasonics"*, Editor, C.R. Hill, Ellis Horwood Series in Applied Physics, John Wiley & Sons, NY 1986; G. S. Kino, *Acoustic waves: devices, imaging and analog signal processing*, Prentice-Hall Inc., New Jersey, 1987]. Taking into account the above, it is seen that when operating at a frequency above 10 MHz and distances above 50 mm, as may be found when operating according to the invention, a decay of 50 - 200 dB is expected.

Measurement of Distance

The following will illustrate a method for measuring the distance between the two elements 1 and 1A of the positioning assembly, according to the two abovementioned preferred embodiments of the invention.

a. Using a separate transmitter and a receiver. When a separate transmitter and a receiver are used, the following two methods will exemplify the measurement of distance:

Counter Method

According to this method when transmission of the ultrasound pulse begins a counter is actuated, which stops its counting when the signal is received in the receiver. While, theoretically, any resolution of the time measurement is possible, very high resolutions require unnecessarily expensive and complicated equipment. For instance, in order to obtain an accuracy of distance measurement of 1μ, if the wave travels in the tissue with a mean speed of 1540 m/s, the frequency of the counter clock should be:

$$T_{clk} = 1\text{Melanie}/1540 \text{ m/s} = 1/6.5\text{x}10^{-10} \text{ s} = 1.5 \text{ GHz}$$

However, much lower resolutions can be employed, of the order of 10-100μ, with a counter frequency of 15-150 MHz.

Correlation Method

The travel time of the wave can also be measured by sampling the signal received and correlating it to the transmitted signal. On the basis of this

calculation it is possible (at the sampling resolution) to measure when the pulse reached the receiver. This is a more precise method, as compared with the counter method, and is therefore preferred for most devices.

b. Using a Transmitter-Receiver. In this case a pulse is transmitted from the transmitter-receiver positioned on either side of the device. For this example we will assume that the transmitter-receiver is positioned on the stomach side (portion "b" of Fig. 5), and at the other side (part "f" of Fig. 5) an "ultrasonic mirror" plays the role of portion 1 of the positioning assembly. At the same time the pulse is transmitted a counter is actuated, which is stopped when the reflected signal is received back by the transmitter-receiver. The distance is calculated as the time measured by the counter, divided by 2 and multiplied by the speed of travel of the wave in the tissue.

This mode has the disadvantage that since the same hardware is used for transmitting and receiving, as long as the transmission of the pulse is not completed no receiving is possible. Accordingly, all reflections reaching the receiver during transmission are not used. Thus, the minimal measurable distance is determined by half the transmission time.

Fig. 16 is a block diagram of an ultrasonic positioning assembly, according to a preferred embodiment of the invention. Existing ultrasound equipment operates either in the so-called "C-MODE" (C-scan), or "A-MODE" (A-scan) (see *"Acoustic Waves"*, Gordon S. Kino, Prentice-Hall, 1987). In the example of Fig. 16 a C-MODE ultrasound is illustrated,

although the same principles can be applied, *mutatis mutandis*, to A-MODE.

A transmitter transducer (or array of them) 100, and a receiver transducer (or an array of them) 101, are separated by tissue 103, consisting of three separate layers: the boundary 104 of the esophagus, the boundary 105 of the fundus, and the fat tissue 106 between them. The timing and control system 107 generates pulses of a frequency of, e.g., 10MHz, with a pulse repetition frequency (PRF) of 100Hz and a pulse width of 8 μsec. The pulses are amplified by the amplifier 108 and reach the transducer 100, where the electrical signal is transformed into an ultrasonic wave. The average size of a suitable ultrasonic transducer is 2-10 mm. Directional transducers are preferred.

The ultrasonic wave passes through tissue 103 and reaches the receiver 101, that translates it into an electric signal which is amplified in amplifier 109. The amplified signal is fed to a signal analysis circuit 110 that performs the following functions:

a. It determines whether the transducers are aligned transversally. This can be achieved by scanning transversally, either manually or automatically, using a servo motor, and determining the maximum in the signal, or in an array by using phase difference.
b. It measures the distance between the two transducers, as previously described, or in any other suitable manner.

The operation of the various elements of Fig. 16 is well known to the skilled person, and is therefore not described herein in detail, for the sake of brevity.

While embodiments of the invention have been described by way of illustration, it will be understood that the invention can be carried out by persons skilled in the art with many modifications, variations and adaptations, without departing from its spirit or exceeding the scope of the claims.

CLAIMS

1. An endoscopic device for the partial fundoplication, comprising:
   - a distal bending portion and a flexible portion suitable to be positioned in extended shape within the esophagus of a subject;
   - a positioning assembly comprising two separate elements, one of which is located on said distal bending portion, and the other on said flexible portion;
   - a stapling assembly comprising a staple ejecting device, wherein said staple ejecting device is located on either said bending portion or on said flexible portion, said staple ejecting devices being in working positioned relationship when said two separate elements of said positioning assembly are aligned; and
   - circuitry for determining when said two separate elements of said positioning assembly are aligned.

2. A device according to claim 1, wherein the stapling assembly further comprises an anvil, wherein one of said anvil and of said staple ejecting device is located on said bending portion, and the other is located on said flexible portion, said anvil and said staple ejecting devices being in working positioned relationship when said two separate elements of said positioning assembly are aligned.

3. A device according to claim 1 or 2, comprising safety means for disabling the operation of the staple-ejecting device when the two separate elements of the positioning assembly are not aligned.

4. A device according to claim 1, comprising viewing means.

5. A device according to claim 4, wherein the viewing means comprise a video camera.

6. A device according to claim 4, wherein the viewing means comprise illumination apparatus.

7. A device according to claim 1, comprising conventional endoscopic devices and accessories.

8. A device according to claim 7, wherein the conventional endoscopic devices and accessories comprise water and/or air supply and/or suction.

9. A device according to claim 1, further comprising a positioning assembly to position a portion of a stapling assembly within the esophagus at a location of about 5-6 cm above the gastroephagel junction, when the endoscopic device is in working position.

10. Apparatus according to claim 9, wherein the portion of the stapling assembly comprises an anvil.

11. Apparatus according to claim 9 or 10, wherein the portion of the stapling assembly is displaced along the axis of the endoscopic device by the action of a flexible threaded cable coupled with a female thread located in said portion of stapling assembly.

12. Apparatus according to claim 11, wherein the flexible threaded cable is located within the endoscopic device, and is in contact with the female thread through a slit provided in the wall of the body of the endoscopic device.

13. Apparatus according to claim 11, wherein the flexible threaded cable is embedded in the external wall of the endoscopic device, and is in direct contact with the female thread of the portion of the stapling assembly.

14. Apparatus according to any one of claims 11 to 13, wherein the flexible threaded cable is rotated using a micrometric assembly, thereby to displace the portion of the stapling assembly positioned within the esophagus by a controlled distance.

15. Apparatus according to claim 10, wherein the anvil is essentially ring-like in shape.

16. Apparatus according to claim 1, wherein the distal portion of the positioning assembly is located on the distal tip.

17. Apparatus according to claim 1, wherein the distal portion of the positioning assembly is located on the outer wall of the distal tip.

18. Apparatus according to claim 1, wherein the distal portion of the stapling assembly is located on the distal tip.

19. Apparatus according to claim 1, wherein the distal portion of the stapling assembly is located on the outer wall of the distal tip.

20. A method for carrying out an endoscopic partial fundoplication of the fundus of the stomach of a patient, comprising the steps of:

(a)providing an endoscopic device comprising a bending portion and a flexible portion, a positioning assembly comprising two separate elements, and a stapling assembly comprising a staple ejecting device;

(b)moving the distal tip of said endoscopic device so as to engage the fundus of the patient and to displace it toward the lower part of the esophagus;

(c) bringing said stapling assembly into working positioned relationship by aligning said two separate elements of said positioning assembly located one on the bending portion and the other on the flexible portion of said endoscope;

(d) determining when said two separate elements of said positioning assembly are aligned by maximizing a signal resulting by bringing them into close positioned relationship

and received at a signal receiving and analyzing circuit cooperating with said positioning assembly;

(e) ejecting a plurality of staples from said staple-ejecting device, thereby to connect the tissue between them; and

(f) rotating the endoscopic device relative to the axis of the esophagus and repeating steps (c) through (e) for as many times as needed to achieve the desired partial fundoplication.

21. A method according to claim 20, wherein the stapling assembly further comprises an anvil, wherein one of said anvil and of said staple ejecting device is located on said bending portion, and the other is located on said flexible portion.

22. A method according to claim 20 or 21, wherein the signal resulting by bringing the two separate elements into close positioned relationship is maximized by measuring a physical parameter which is a function of the distance.

23. A method according to claim 20 or 21, wherein the signal resulting by bringing the two separate elements into close positioned relationship is maximized by correlating it to a measured physical parameter.

24. A method according to claim 21, wherein the distance between the staples ejecting device and the anvil is between about 0.5 and 1.5 cm.

25. A method for positioning the endoscopic device of claim 1 in pre-aligned working position, comprising the steps of:

a) introducing the endoscopic device through the mouth of a patient and locating the position of the gastroesophageal junction;

b) determining the distance from a reference point located on the endoscopic device, and the gastroesophageal junction;

c) introducing the endoscopic device into the stomach by a length below the gastroesophageal junction sufficient to permit the distal tip to be flexed into a position where the fundus is pushed toward the esophagus;

d) locking the endoscopic device such that it cannot move relatively to the axis of the esophagus;

e) determining the position of the portion of the stapling assembly positioned within the esophagus using its original axial location, the distance determined in step b) above, and the radius of curvature of the distal portion of the endoscopic device; and

f) displacing said portion of the stapling assembly so as to position it in the range of about 5-6 cm above the gastroesophageal junction.

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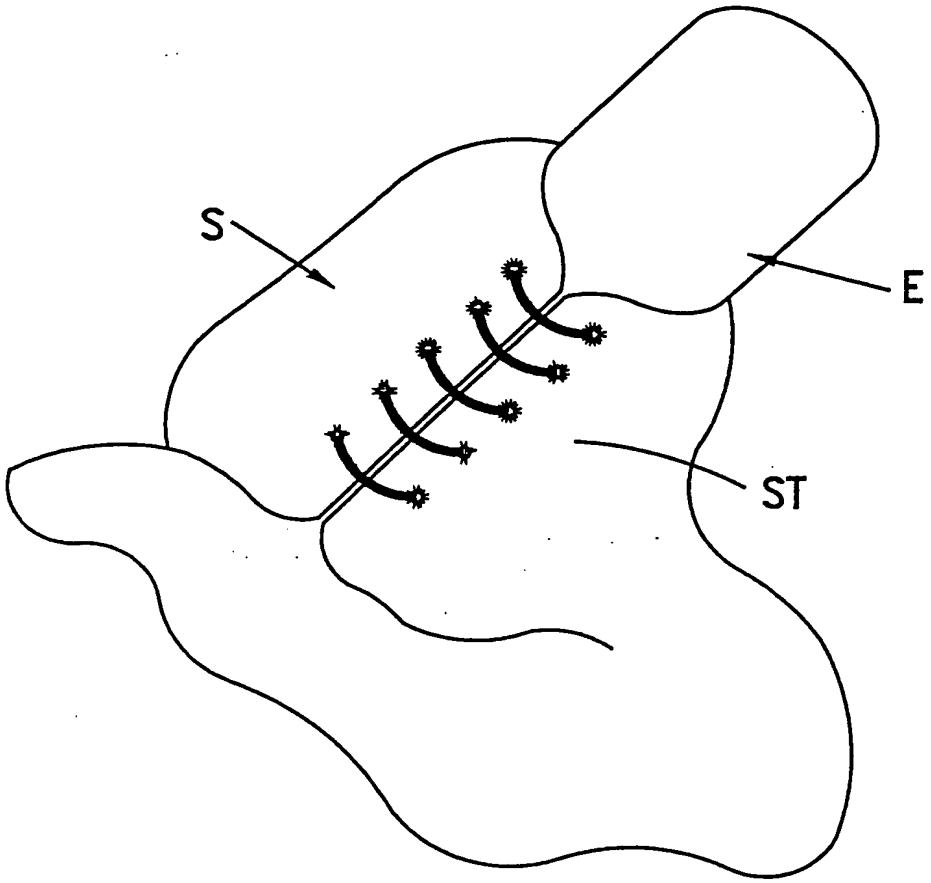

Fig. 1(Prior Art)

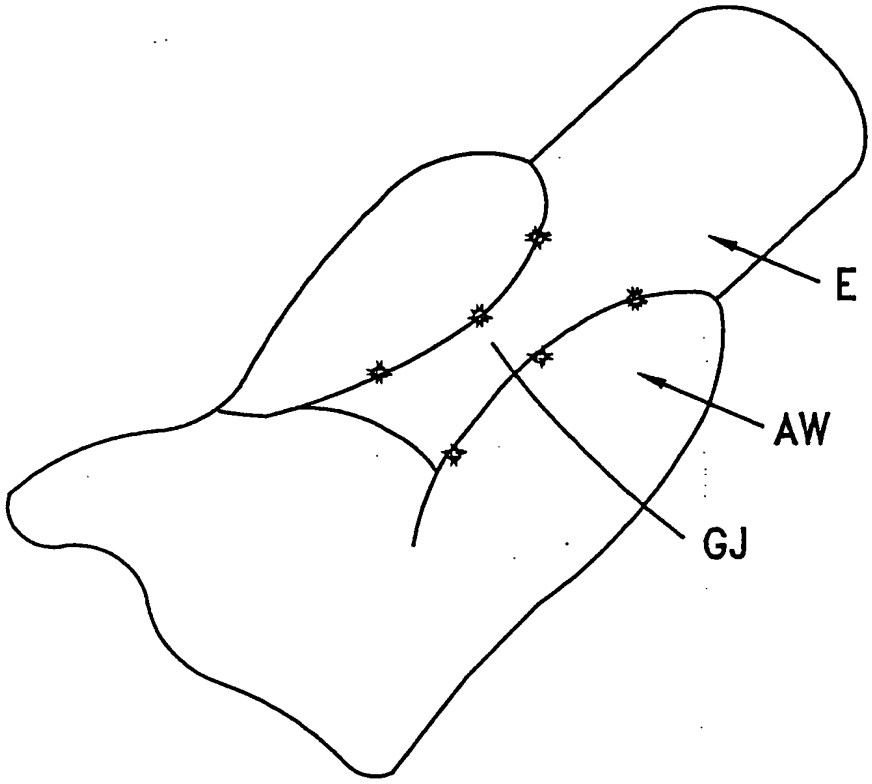

Fig. 2(Prior Art)

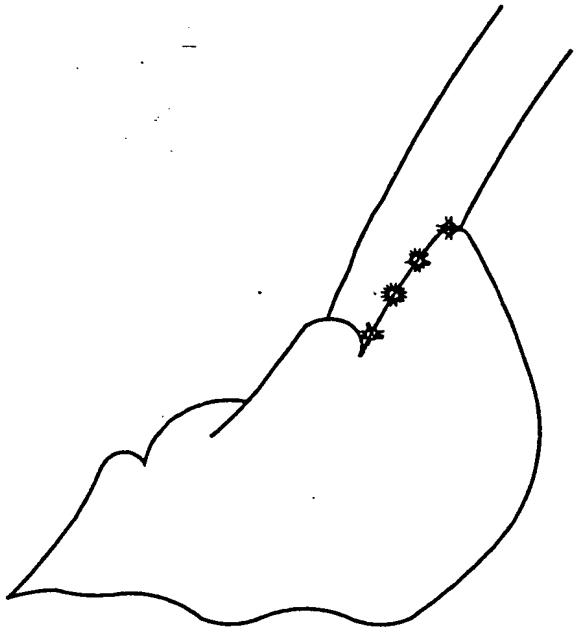

Fig. 3(Prior Art)

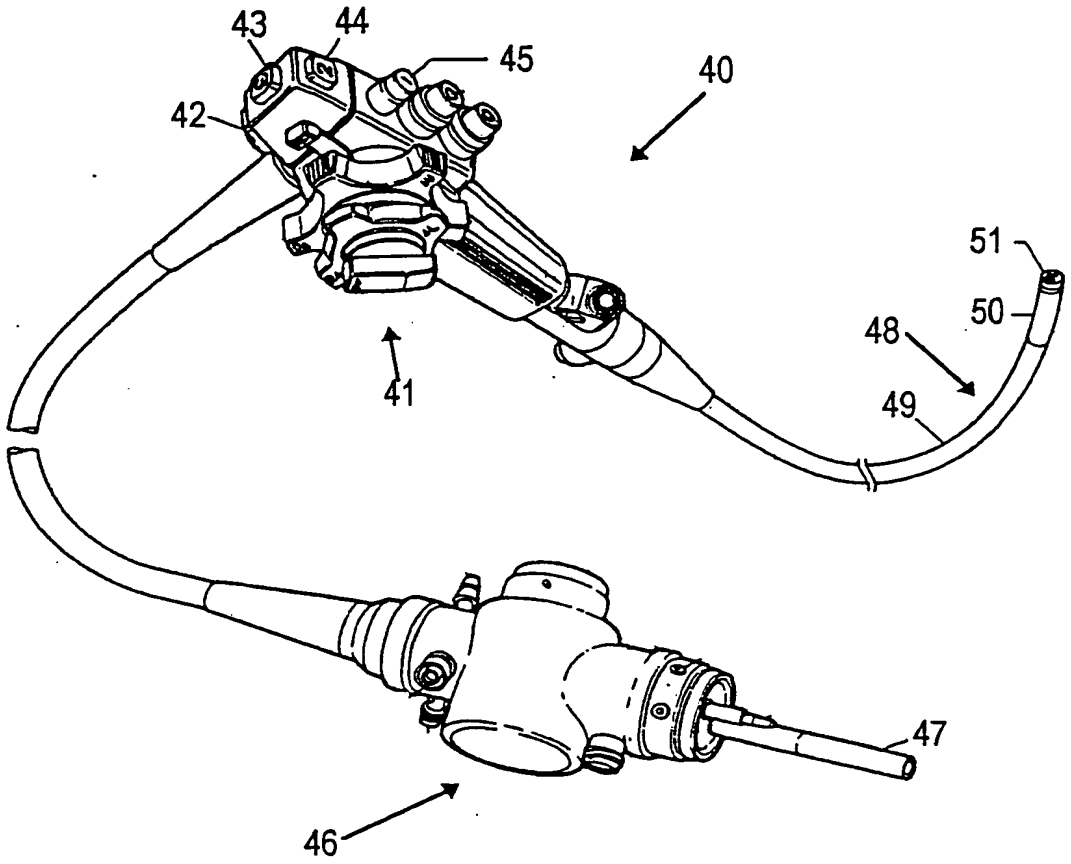

Fig. 4A

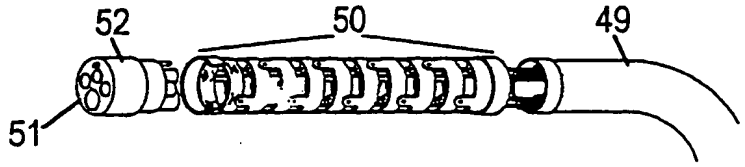

Fig. 4B

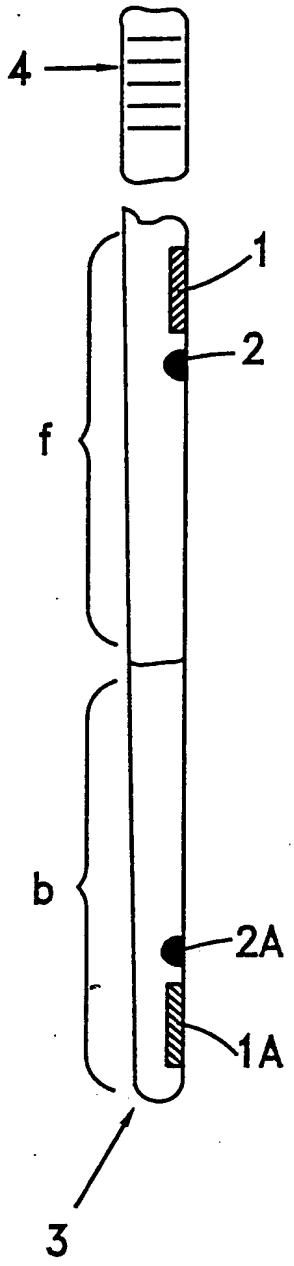

Fig. 5

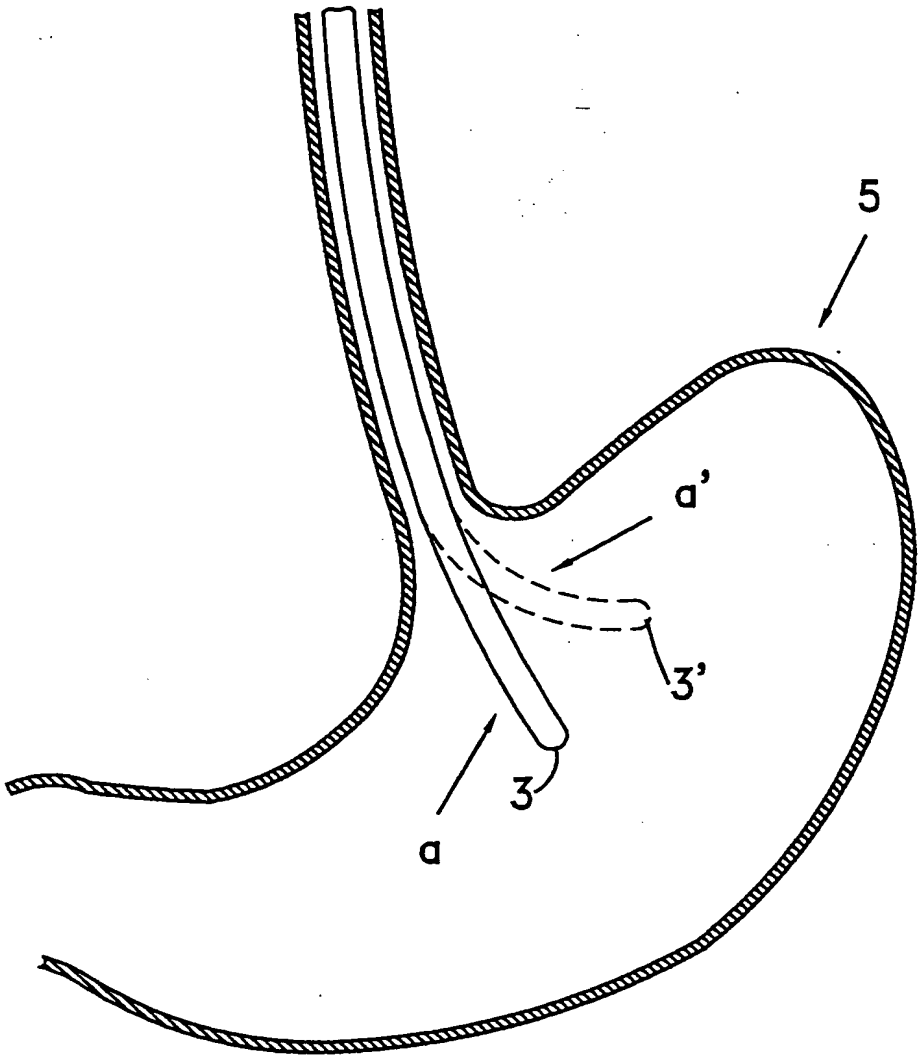

Fig. 6A

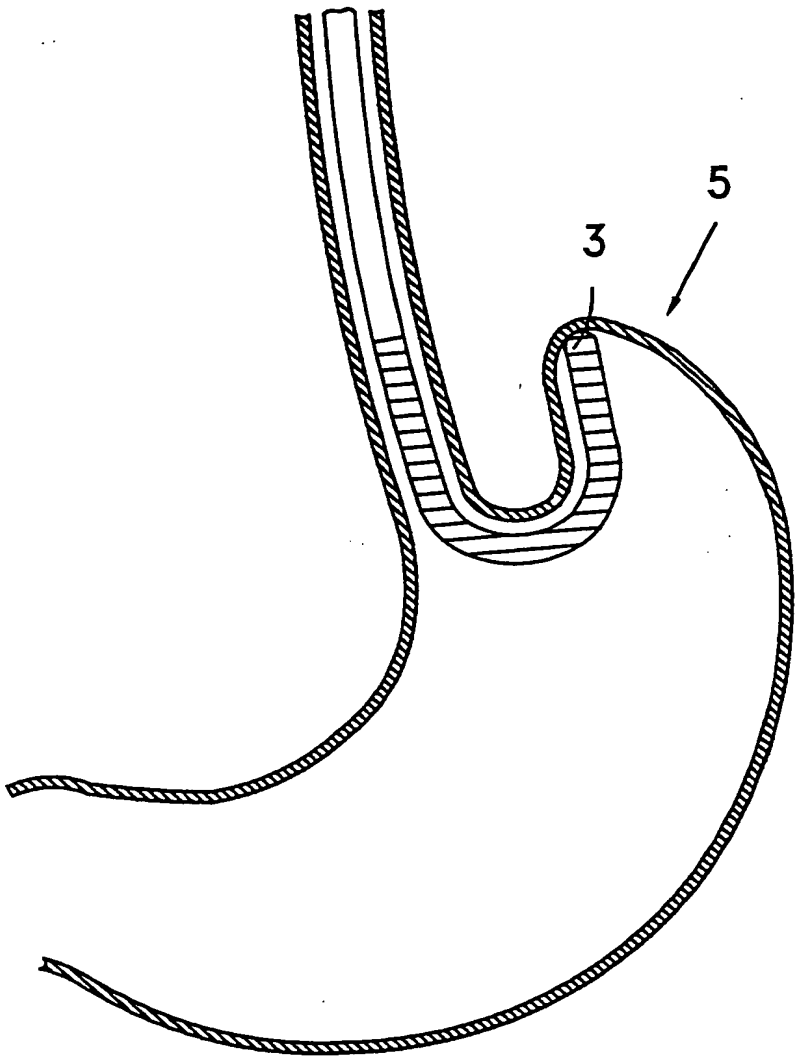

Fig. 6B

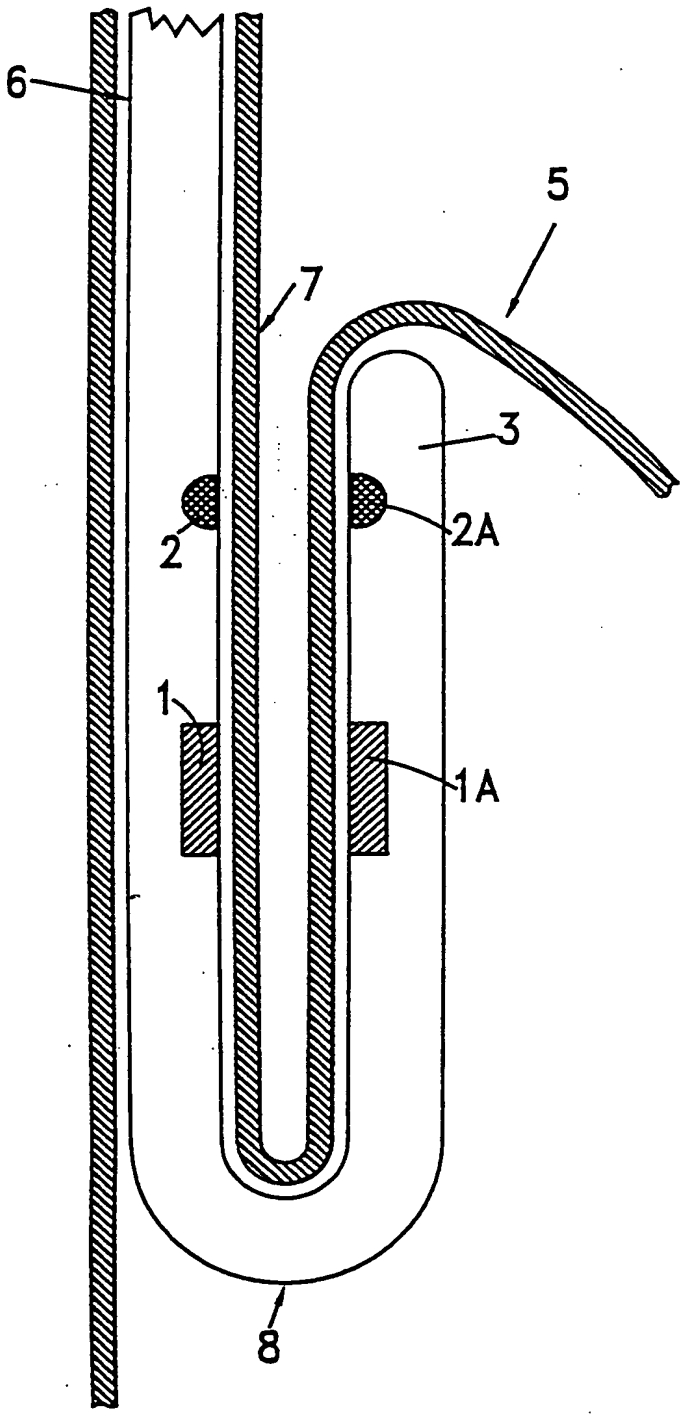

Fig. 7

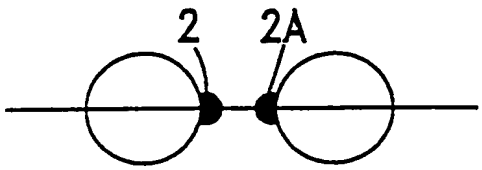

Fig. 8A

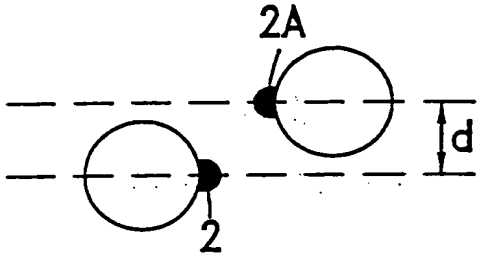

Fig. 8B

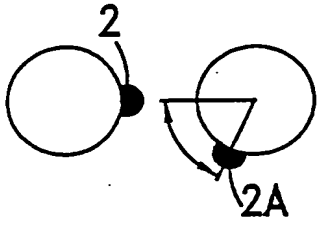

Fig. 8C

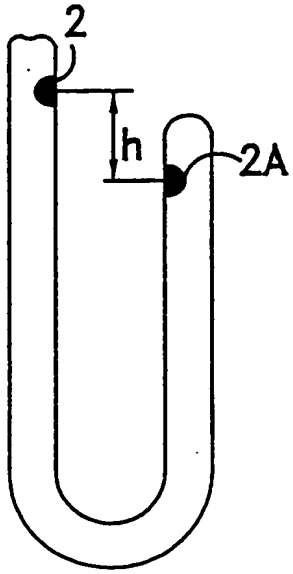

Fig. 8D

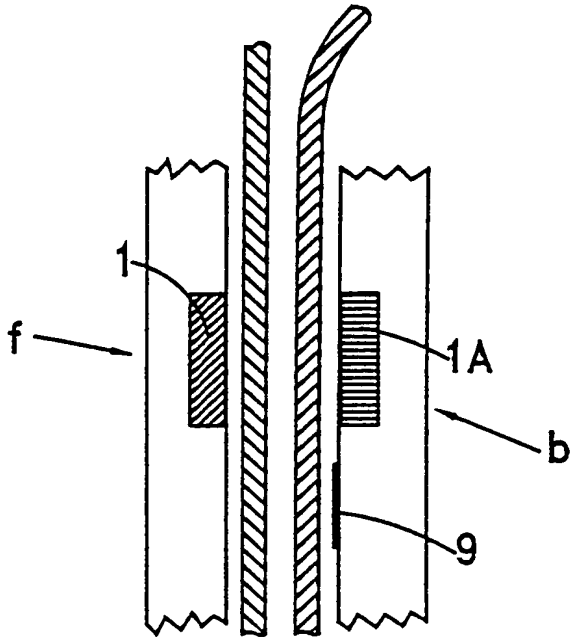

Fig. 9A

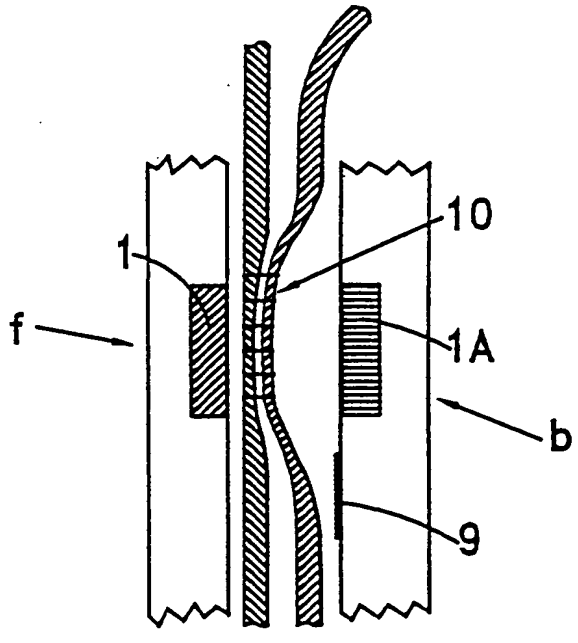

Fig. 9B

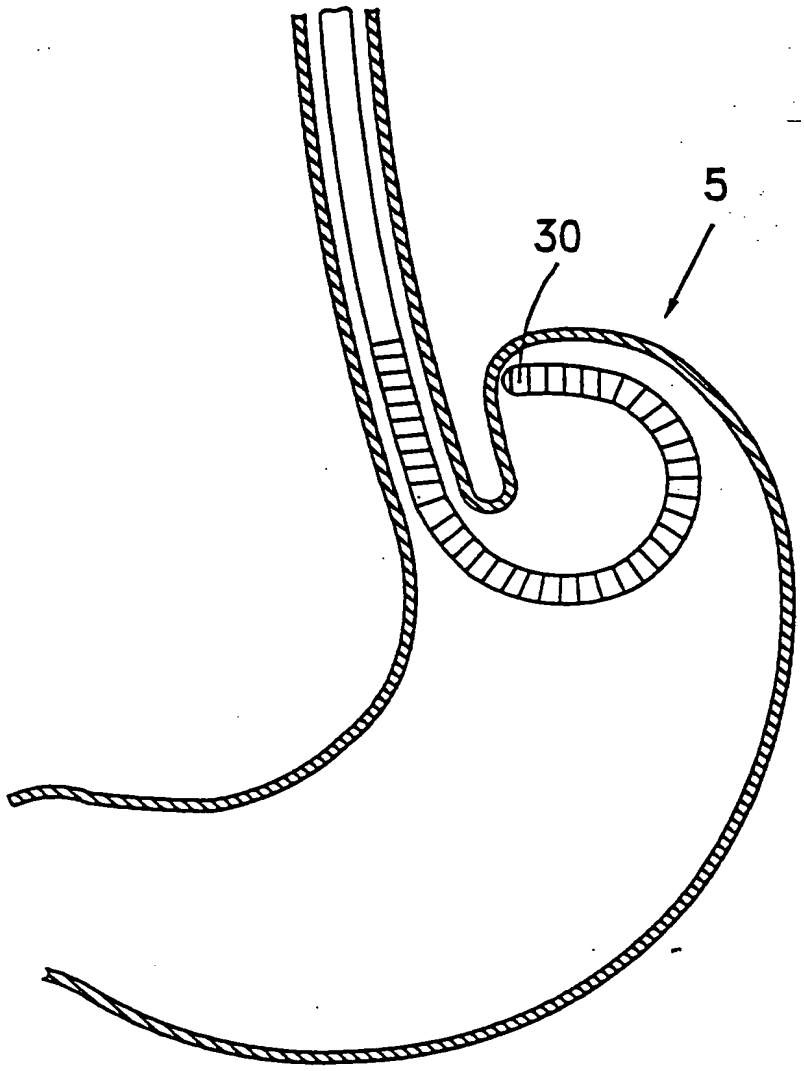

Fig. 10

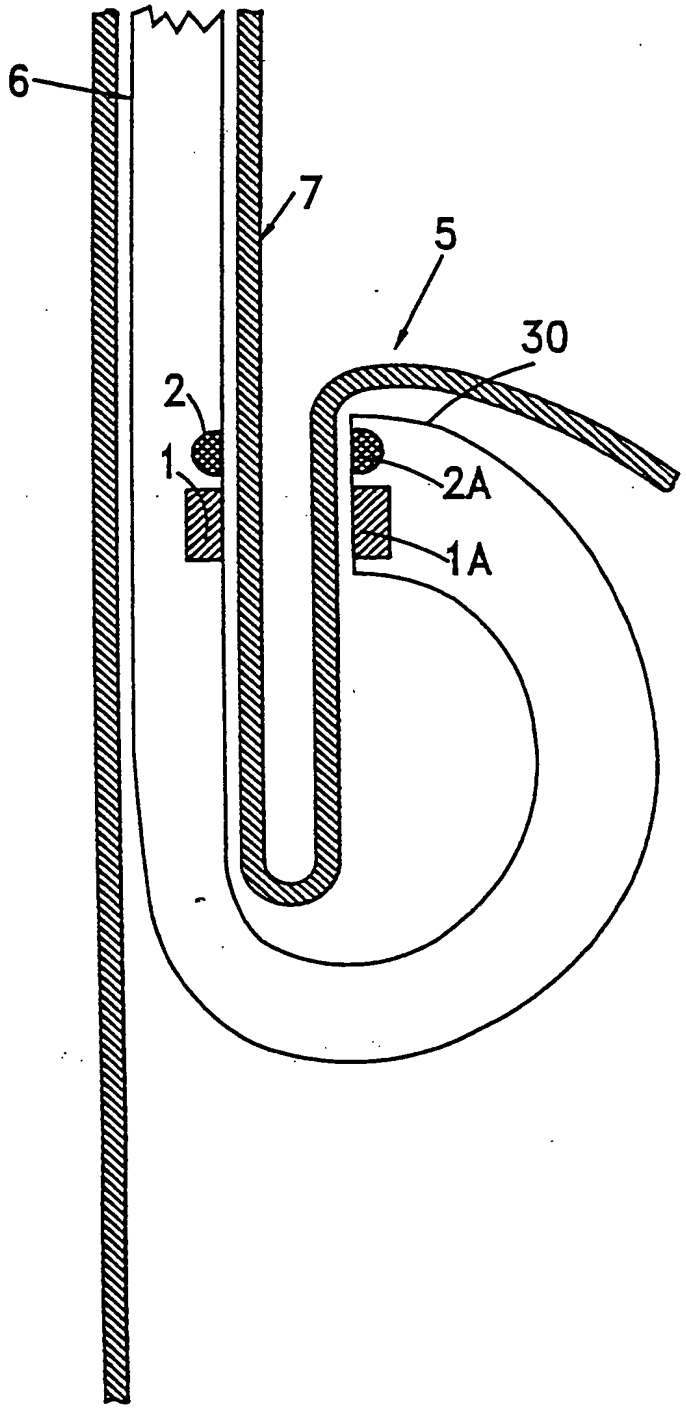

Fig. 11

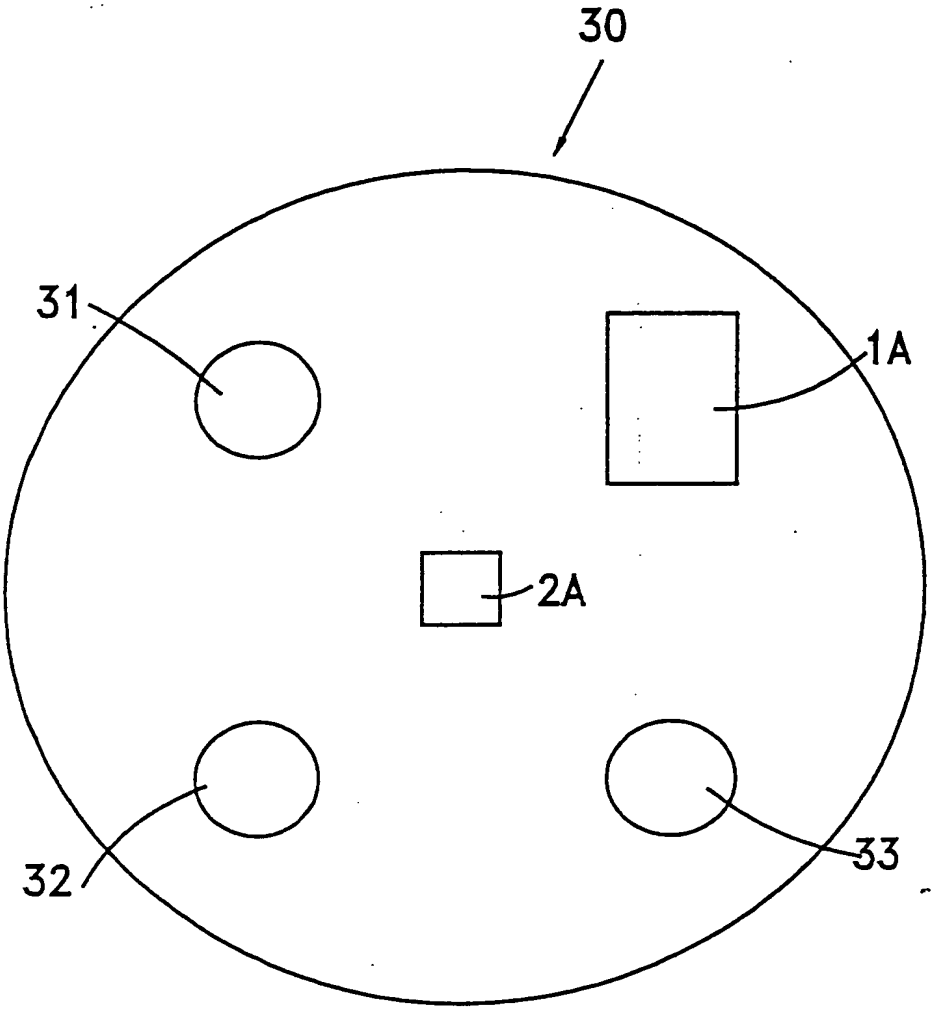

Fig. 12

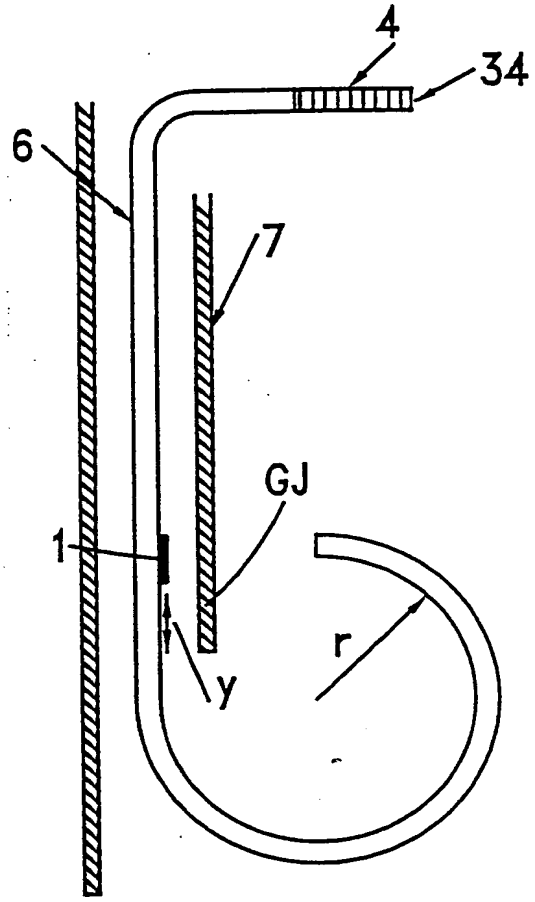

Fig. 13

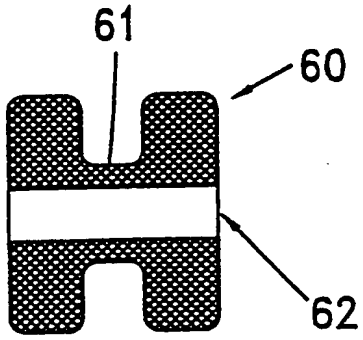

Fig. 14

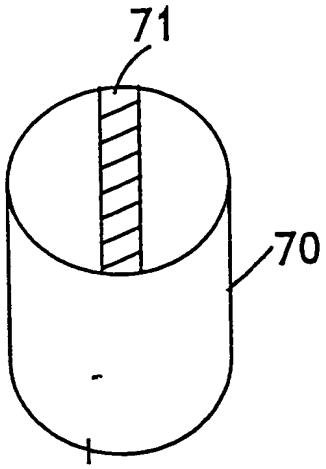

Fig. 15A

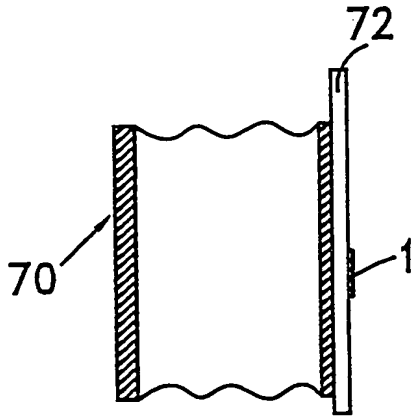

Fig. 15B

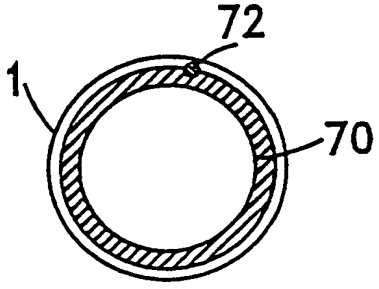

Fig. 15C

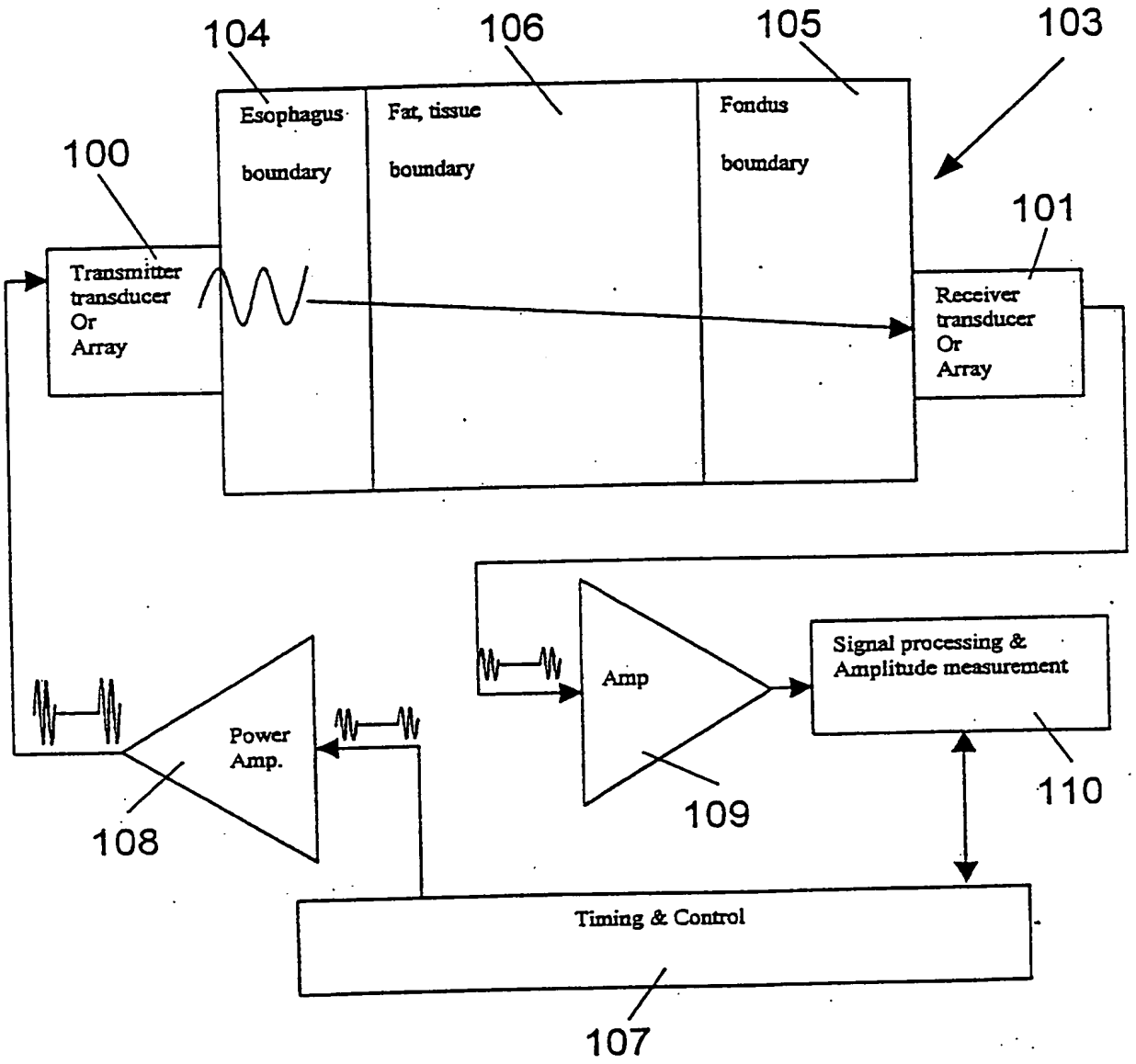
104
106
105
103
Esophagus
boundary
Fat, tissue
boundary
Fondus
boundary
100
101
Transmitter
transducer
Or
Array
Receiver
transducer
Or
Array
Amp
Signal processing &
Amplitude measurement
Power
Amp.
108
109
110
Timing & Control
107

Fig. 16